S 3130

Safe Reprocessed Medical Devices Act of 2002

Congress: 107 (2001–2003, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Oct 17, 2002
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Oct 17, 2002)
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Sponsor

Name: Sen. Durbin, Richard J. [D-IL]
Party: Democratic • **State:** IL • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Gregg, Judd [R-NH]	R · NH		Oct 17, 2002

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Oct 17, 2002

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Oct 17, 2002)

Safe Reprocessed Medical Devices Act of 2002 - Classifies as misbranded a device that is reprocessed and intended for use on a single patient, unless such product meets certain requirements, including that it: (1) is labeled with the number of times it has been reprocessed; and (2) prominently and conspicuously bears an identification of the reprocessor and the original manufacturer. Allows the Secretary to waive the latter requirement.

Directs the Secretary of Health and Human Services to review, according to specified criteria, a Class I or Class II reprocessed device whose producer is exempt from having to report preceding the device's introduction into state commerce. Requires the Secretary to publish in the Federal Register a list of such devices that are no longer exempt.

Declares that the termination of an exemption from reporting requirements for a reprocessed device shall not terminate the exemption for the original device.

Directs the Secretary to perform specified duties with respect to those reprocessed single-use devices that require reports, including to require validation data. Prohibits the Secretary from determining that such a device is misbranded or adulterated or from taking action against the device for a failure to provide certain required information unless one of specified conditions are met, including that the device is not substantially equivalent to a predicate device. Prohibits marketing the device if it is not substantially equivalent.

Actions Timeline

- **Oct 17, 2002:** Introduced in Senate
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